that Samo administers 40 x 10^6 *units* of interferon. However, a unit of interferon is to be distinguished from an International Unit. A unit is routinely defined as about one-tenth the quantity of interferon represented by one International Unit. See, for example, Cummins patent 5,019,382, Col. 3, lines 45 - 55. Thus, the actual dose of interferon administered by Samo is 4 x 10^6 IU, a significantly lower dose composition than the presently claimed composition. Further, Samo uses as little as 0.2 to 0.004 of the dosage disclosed in the instant invention.

Second, Samo et al. actually teach away from the present invention. Throughout the paper the authors note that significant local side effects accompany the use of this composition, i.e., nasal irritation, mucosal erosion and blood mixed with mucus. See, for example, the concluding line of the Abstract. Samo would not provide the skilled artisan with the motivation to prepare an even higher dose composition, which would be expected to cause even more frequent or more severe side effects. No side effects, or other pathology, were noted in the current study.

Finally, the Samo reference teaches the use of interferon for the treatment of a viral infection. There is no indication that this would be useful in treating a neoplastic condition. Thus, one skilled in the art would not be motivated to prepare ultra-high dose interferon compositions for the treatment of any disease without eliciting a pathological response, let alone a neoplastic disease. High dose compositions are neither taught nor suggested by Samo.

Rejection under 35 USC §103 of Claims 6, 13 and 17-20

Claims 6, 13 and 17-20 stand rejected under 35 USC §103(a) as being unpatentable over Cummins et al. Cummins allegedly teaches the oromucosal administration of interferon for treating neoplastic disease and, thus, provides the motivation for the claimed methods and composition. Applicants respectfully disagree.

The Cummins patent teaches the administration of less than about 5 IU/lb (11 IU/kg) per day for the treatment of neoplastic disease. Thus, Cummins, as stated at Column 1, lines 6 - 14, relates to the use of "interferon in low oral dosages." As further stated at Column 12, lines 17 - 20, the human therapy consisted of oral administration of 0.7 IU per pound of patient body weight per day. Assuming a 154 lb human (70 kg), a greater than 10^5 increase in dosage would be necessary to come within the claims of the instant invention. Indeed, the present invention utilizes ultra-high doses, i.e. >20 x 10^6 IU interferon per 70 kg human (>285,000 IU/kg), to treat a neoplastic condition. The Cummins patent discloses and is limited to the administration of an interferon dosage of less than about 5 IU/lb. Nowhere in the Cummins patent is it taught or suggested that a dosage larger than about 5 IU/lb could be administered. Furthermore, one of skill in the art would not be motivated to use the ultra-high doses used by Applicants because of the reported toxicity of interferon.

Rejection Under 35 USC §112, first paragraph

Claims 6 and 13 stands rejected under 35 USC 112, first paragraph, as lacking enablement for the claimed subject matter which Applicants regard as the invention. Specifically, the Examiner alleges that the specification, while being enabling for the neoplastic conditions disclosed, does not reasonably enable the term "neoplastic condition." Applicants have amended the claims so that the neoplastic conditions known to be sensitive to interferon are specifically claimed, recognizing that future approved indications are within the scope of the claim.

For the foregoing reasons, applicants respectfully request that the rejections be withdrawn.

Conclusion

The instant invention is drawn to the use of ultra-high dose oromucosal interferon for the treatment of neoplastic conditions. The newly added claims further define and limit the invention to such uses and conditions. The prior art fails to suggest or teach such a use of ultra-high dose interferon or such an ultra-high dose interferon composition.

All rejections having been addressed, reconsideration of the application in view of the foregoing amendments and remarks, and an early indication of allowability of Claim 6, 13, and 17 - 33 are earnestly solicited.

Respectfully submitted,

William Schmonsees
Attorney for Applicants
Reg. No. 31,796

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Heller Ehrman White & McAuliffe
525 University Avenue
Palo Alto, CA 94301-1900
(650) 324-7041

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